

# Notice of Allowability

Application No.

10/736,511

Examiner

Maria Veronica D. Ewald

Applicant(s)

KUSHIKU ET AL.

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## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 6/8/06.
2. ☒ The allowed claim(s) is/are 19-27.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☒ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☒ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

**EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Shelly Cermak on June 20, 2006. Claims 1 – 17, which were previously withdrawn, have been cancelled.

The following is an examiner's statement of reasons for allowance: Prior art fails to teach a diL-lysine monosulfate trihydrate crystal, characterized by having peaks at diffraction angles  $2\theta$  of  $16.6^{\circ}$  and  $17.0^{\circ}$  as measured by powder X-ray diffraction. In addition, prior art does not teach a composition comprising diL-lysine sulfate wherein said diL-lysine sulfate is prepared by the method of a) mixing a lysine-based solution with sulfuric acid at a temperature of between approximately  $-10^{\circ}\text{C}$  and approximately  $35^{\circ}\text{C}$ ; and allowing crystals to form, which are characterized by having peaks at diffraction angles  $2\theta$  of  $16.6^{\circ}$  and  $17.0^{\circ}$  as measured by powder X-ray diffraction, b) recovering said crystals and c) drying said crystals and further fails to teach a composition comprising diL-lysine monosulfate trihydrate crystal, wherein the diL-lysine monosulfate trihydrate crystal is prepared by the method of a) mixing a lysine-based solution with sulfuric acid at a temperature above approximately  $40^{\circ}\text{C}$ , and allowing crystals to form characterized by having peaks at diffraction angles  $2\theta$  of  $16.6^{\circ}$  and  $17.0^{\circ}$  as measured by powder X-ray diffraction, b) lowering the temperature until it is

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between approximately  $-10^{\circ}\text{C}$  and approximately  $35^{\circ}\text{C}$ ; and allowing crystals to form, c) recovering said diL-lysine monosulfate trihydrate crystal, and d) drying said diL-lysine monosulfate trihydrate crystal.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Veronica D. Ewald whose telephone number is 571-272-8519. The examiner can normally be reached on M-F, 8 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Yogendra Gupta can be reached on 571-272-1316. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MVE

  
**ROBERT KUNEMUND**  
**PRIMARY EXAMINER**